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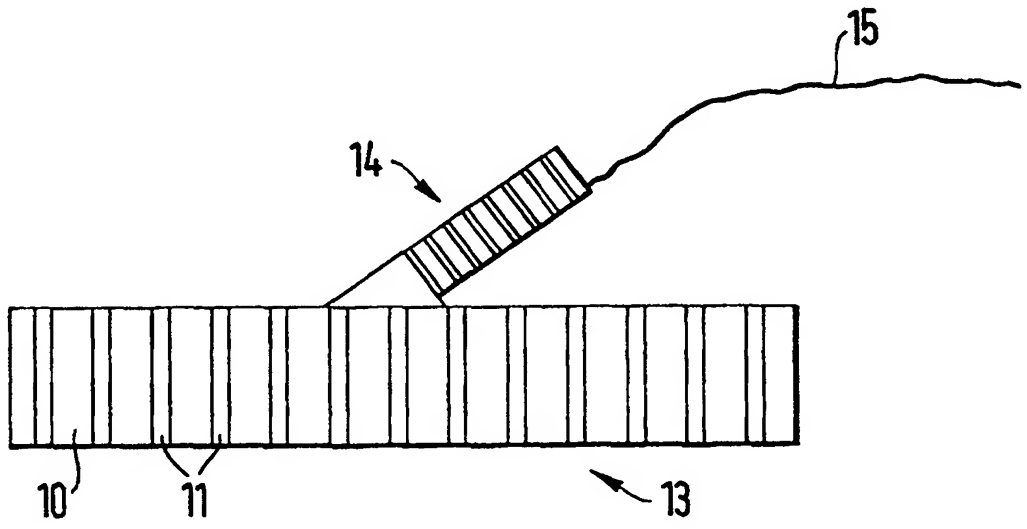
(54) Title: A SURGICAL GRAFT/STENT SYSTEM



(57) Abstract

A tubular graft/stent comprises a tubular sheath (10) having at intervals along its length a plurality of ring-like rigid members (11), which are attached to the sheath around their respective circumferences and are made of a shape memory material, so that when said members (11) change shape the sheath (10) adopts a new cross section in conformity with them along its whole length. The members may be discontinuous to allow the adoption of a contracted shape in the martensitic phase and an expanded shape in the austenitic phase. A graft may also have a side tube (14) which can be inverted so as to be housed within the sheath.

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A SURGICAL GRAFT/STENT SYSTEM

This invention relates to a graft/stent system for use in human or animal surgery.

The invention proposes a medical tubular graft stent which comprises a tubular sheath having at intervals along its length a plurality of ring-like rigid members, wherein said members are attached to the sheath around their respective circumferences and are made of a shape memory material, so that when said members change shape, the sheath adopts a new cross-section in conformity with them along its whole length.

Preferably, this provides a compliant tubular sheath, into which a series of open rings are integrated. The rings act as rigidising members and are capable of being radially compressed by mechanical forces in the martensitic phase so as to reduce the diameter, and of then returning in the austenitic phase to a memorised, larger diameter by a thermal effect.

In a further aspect, the invention proposes a tubular graft comprising a tubular sheath having a branch tube which is sufficiently flexible to be inverted so as to be housed within the sheath during an insertion operation in a human or animal body, and to be redeployed as a branch after said operation. The sheath and/or the branch tube may employ annular rigid members of a shape memory material, as explained above. In all cases, the members are preferably discontinuous, e.g. a ring with a break so as to facilitate compression and re-expansion.

In order that the invention shall be clearly understood, several exemplary embodiments thereof will now be described with reference to the accompanying drawings, in which:

Fig. 1 shows a perspective view of a first form of graft;

Fig. 2 shows its compressed form in the martensitic phase in transverse cross-section;

Fig. 3 shows its expanded form in the austenitic phase;

Fig. 4 shows an embodiment having a branch tube in its inverted position;

Fig. 5 shows the Fig. 4 version with the branch tube deployed;

Fig. 6 shows a further embodiment of the present invention; and

Figs 7 and 8 show enlarged and developed views of two versions of an overlap region.

An exemplary general arrangement is shown in Fig. 1. A compliant tube 10 can be constructed of any flexible material such as cloth, polymers, elastomers or gels. Secured within the compliant tube are a plurality of expandable or contractible open rings 11 composed of shape memory alloy material. The shape memory alloy rings give structural support to the compliant tubular sheath and are oriented transverse to the axis of the tube. The tube is circumferentially closed by the overlap 20, but has free edges 21, 22. Alternatively, the edges 21, 22 might butt one another, but this does not provide as much certainty that the tube wall is closed.

The compliant tube 10 can be generated by fabrication methods, or an "open" tube could be made by using flat sheets whose shape is established by the shape memory alloy rings. The tubular form might also use sheets of dissimilar materials. The tube may be produced in continuous lengths and cut off as needed.

The shape memory alloy rings can be retained by casting a suitable compliant material around the rings, by adhesive bonding, sewing or by generating a series of pockets within which the rings may be held by welding, sewing, mechanical fixation or adhesive bonding. In the embodiment shown, the rings 11 are in a single piece, but could be in two or more arcuate sections.

Figs. 2 and 3 show the compressed (e.g. spiral or rolled-up) and expanded forms of the tube. The tubular graft/stent is radially compressed down to 5.5 mm outside diameter before the device is fitted into the human body via a delivery catheter. In its expanded form, the outside diameter might be up to 4 cm.

The device described is suitable for a number of minimally invasive surgical techniques or may substantially reduce trauma associated with the introduction of implanted medical devices within a living organism. A single, plain tube (known as a tubular graft) with integrated expandable/ contractible rings (known as stents) as described is inserted into an occluded fluid carrying vessel or a vessel that has a stricture. When appropriately positioned via the catheter, heat from the human body (or a heated fluid introduced) will cause the latent geometry of the shape memory alloy to be re-called. Under these circumstances the rings will expand to a pre-determined position as seen in Fig. 3, the outside dimensions of which will be slightly larger than the inner dimensions of the fluid carrying vessel. Frictional effects will normally retain the graft/stent in position. However, the shape memory alloy may be arranged so that when a thermal transition point (memory re-call) is reached selected sections of the alloy will protrude from the metals surface presenting a substantial fixation force. One or more of the alloy rings could be configured with this additional retention feature.

This device may find applications in surgical repair or maintenance procedures for the human body or other animal species. Gastro-intestinal system connections, oesophageal cancer, aneurysms, coronary by-pass connections and

other vascular by-pass or shunt procedures could employ the stent/graft device.

The dynamic properties of the rings expand the graft/stent within the body to effect an opening of constricted or occluded vessel. The outer graft sheath would assist in preventing occlusive material from once again entering the vessel. The compliant sheath will also exclude tumorous growth, maintaining luminal patency.

The tubular graft with integrated shape memory alloy rings may be a simple tube-like form as described or could be a manifold system having a main tube 13 from which one or substantial numbers of connections 14 may be made, as seen in Figs. 4 and 5. The single tube or manifold will allow fluids to pass in or out of the said connections, to or from the main tube structure. The branches extending from the main body can be of uniform cross-section or of tapering construction.

A tubular graft of the type described might be simply bifurcated or may have numerous smaller or larger tubes of similar construction, attached to the main tube body. The branches attached to the body of the device may have a similar shape memory alloy ring configuration. Each branch 14 can be inverted so as to fit within the main tube. Under these conditions, the whole assembly can be radially compressed, the manifold system now appearing as a single tube for initial insertion via a catheter. A suitable cord 15 is connected to the inverted branch enabling it/them to be re-inverted by pulling the cord, as shown in Fig. 5. Preferably, the rings nearer to the main tube are largest and are progressively smaller towards the end, to allow the inversion to occur.

When warmed, the shape memory alloy rings will expand to a pre-determined position. If employed in a surgical repair, forces exerted by the shape memory alloy rings will be of sufficient magnitude to open an occluded vessel thus

enabling appropriate fluid flows to continue.

The compliant outer sheath would enable radial or axial movement of the vessel to occur. This might be the case if the stent/graft were positioned in an oesophagus that had radially disposed tumours. Peristalsis effects used to assist transportation of food and liquids in the human body would need to be maintained in oesophageal dysfunctional problems. The covered or sheathed stent system would exclude tumorous in-growth and still enable peristalsis to occur.

The compliant material could be 0.050 mm polyurethane, polyester or polythene. The shape memory material may be a metal alloy with this property, or alternatively certain mouldable plastics materials such as homopolymers of lactide or glycolide, or copolymers of lactide and glycolide.

The invention is also considered to include a graft with a side tube which does not employ stents of shape memory material. Thus in addition to shape memory materials, the ring-like rigid members 11 can also be fabricated from elastic materials such as stainless steel or the super-elastic forms of nickel-titanium alloys. In this case, the implant is constrained within an outer sheath after whose removal the graft will expand to adopt its final shape.

In the embodiment of Fig. 6, which is of particular benefit in stenting tortuous vessels such as the male urethra, the flexible tubular sheath can contain slits or openings 23 which are approximately parallel to the ring-like members and which allow greater flexion of the implant without kinking the sheath. The arrangement of the slits or openings can be varied with the application and can be positioned to be all on one side of the tube 23, on alternating sides 24 or spirally arranged along the sheath (25). Other arrangements are possible.

The overlap 20 can be designed to have one of three properties:

1) The overlap can be left to slide freely over itself, permitting the graft assembly to be contracted by muscles in the vessel or to allow pressure pulses in arterial blood, arising from the heartbeat, to be transmitted to the artery wall. The action of pressure pulses is involved in maintaining the vasomotor tone in blood vessels.

The mating surfaces of the overlapping part of the sheath can be coated to reduce friction and wear with materials such as PTFE or diamond-like coatings.

2) As shown in Fig. 7, the overlap can incorporate a ratchet-like mechanism which will allow the diameter of the ring-like rigid member to expand but not to contract. This will guarantee that the lumen of the vessel will be maintained to a minimum diameter and will allow the ring to be locked against the inside of the vessel wall to prevent migration of the device.

3) As shown in Fig. 8, the overlap can incorporate a ratchet-like mechanism which will allow the diameter of the ring-like rigid member not to exceed a specified diameter. This is of use where the vessel is fragile and can be exposed to high intraluminal pressures.

The ratchet-like mechanism can be incorporated onto the walls of the sheath by moulding, machining, or attaching ratchet components. Alternatively, the ratchet mechanism can be formed in the ends of the ring-like member and can be either permanently present or deployed by the action of thermal memory.

An implant can be assembled which incorporates a combination of all three types of overlap mechanism so that for instance, the distal ends of the graft can use ratchet expanding rings to lock the device in place, while the main body of the

graft uses alternating sliding and diameter-limiting rings to allow limited transmission of pulsatility while restricting the maximum diameter of the graft.

The benefit of the graft can be increased by incorporating coatings onto its inner or outer surfaces. These coatings can be biomimetics such as phosphorylcholines and proteins, organic biocompatibles such as hydrophillic plastics and inorganic coatings, such as diamond-like carbon. The coatings can be used to be thrombus-resistant, encrustation resistant or to promote cellular ingrowth. In addition, the coatings can be used to release locally acting pharmacological agents and they can be multiply layered.

Deployment of the inverted segment 14 can be achieved by adding a short handle, tab or strip to the distal end of the side branch which can be engaged by a snare, forceps or similar engagement means.

CLAIMS

1. A tubular graft/stent which comprises a tubular sheath (10) having at intervals along its length a plurality of ring-like rigid members (11), which are made of a shape memory material, so that when said members (11) change shape the sheath (10) adopts a new cross-section in conformity with them along its whole length.

2. A tubular graft/stent as claimed in claim 1, wherein the rigid members (11) are attached to the sheath around their respective peripheries.

3. A tubular graft/stent as claimed in claim 1, wherein said members (11) are discontinuous to allow them to adopt a contracted shape in the martensitic phase, and an expanded shape of larger circumference in the austenitic phase.

4. A tubular graft/stent as claimed in claim 1 or 2, wherein said members (11) can be caused to adopt a spiral form as the contracted shape and a generally circular form as the expanded shape.

5. A tubular graft/stent as claimed in any of claims 1 to 3, wherein the members (11) are embedded in a compliant material forming the sheath which is cast around them.

6. A tubular graft/stent as claimed in any of claims 1 to 3, wherein the members (11) are trapped in pockets formed in the material of the sheath.

7. A tubular graft/stent as claimed in any of claims 1 to 3, wherein the members (11) are trapped between two layers of material which together form the sheath.

8. A tubular graft/stent as claimed in any preceding claim, wherein the members (11) include portions which project from the outer surface of the graft in its new cross-section, such projecting portions forming anchors for locating the graft in position in a body.

9. A tubular graft/stent as claimed in any preceding claim, comprising a further graft (14) which branches off the sheath (10), said further graft being capable of inversion so that it is located within the sheath (10).

10. A tubular graft/stent as claimed in claim 8, wherein the further graft (14) has a construction as defined in claim 1.

11. A tubular graft/stent as claimed in claim 9, wherein the rigid members of the further graft (14) are of progressively smaller size in the direction progressively away from the tubular sheath (10).

12. A tubular graft/stent as claimed in claim 8, 9 or 10, wherein the further graft (14) has a draw string attached at its free end such that when inverted into the sheath (10) the draw string may be pulled to redeploy the further graft outside the sheath.

13. A tubular graft comprising a tubular sheath having a branch tube which is sufficiently flexible to be inverted so as to be housed within the sheath during an insertion operation in a human or animal body, and to be redeployed as a branch after said operation.

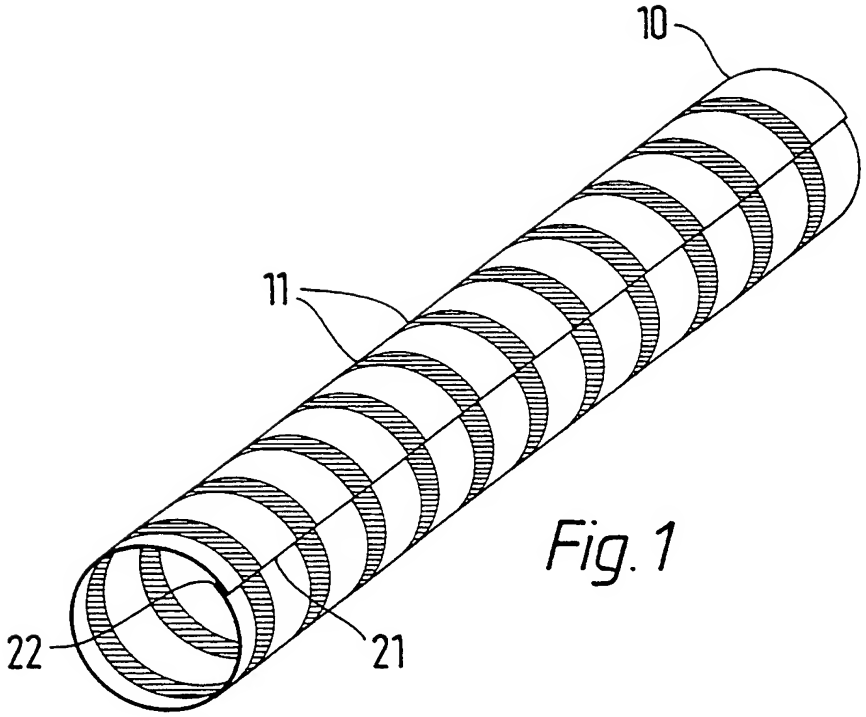

Fig. 1

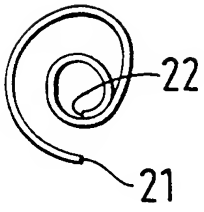

Fig. 2

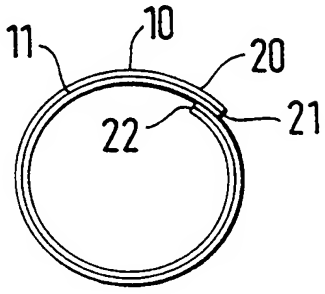

Fig. 3

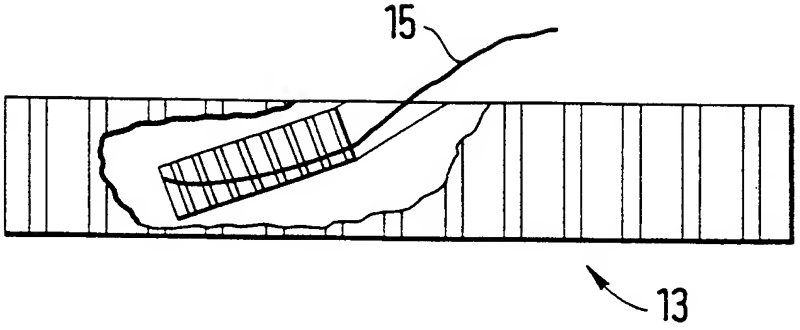

Fig. 4

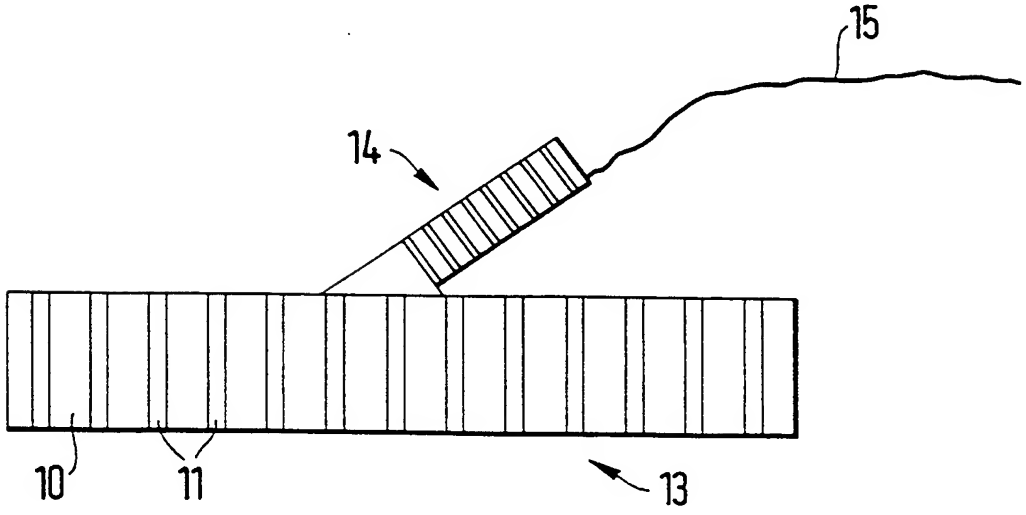

Fig. 5

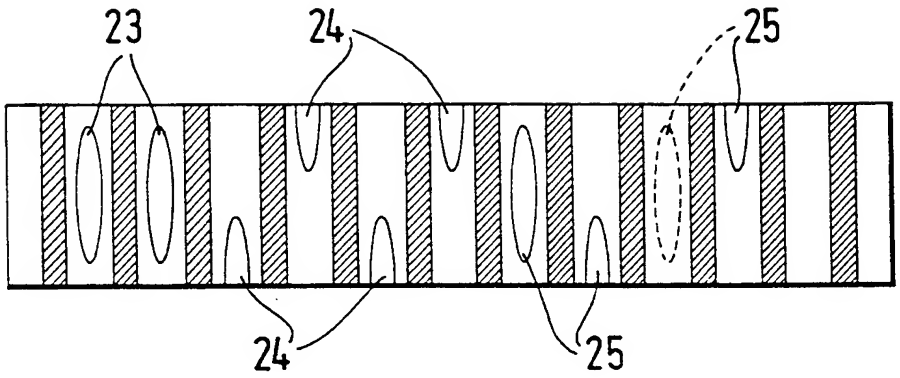

Fig. 6

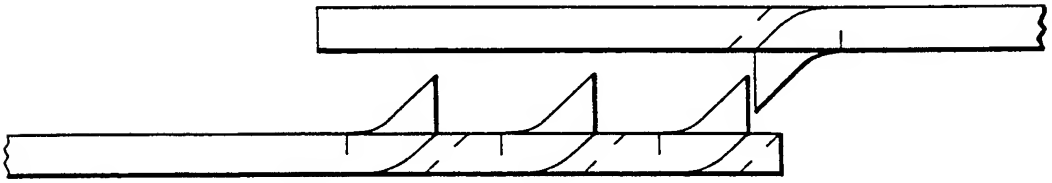

Fig. 7

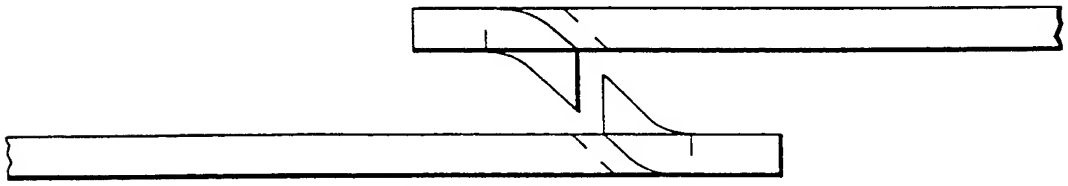

Fig. 8

INTERNATIONAL SEARCH REPORT

Inter. ional Application No
PCT/GB 96/02212

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 326 426 (NIPPON MEDICAL SUPPLY) 2 August 1989 see page 5, line 3 - line 18 see figures 9,10	1-6
Y	---	7,8
Y	FR,A,2 694 688 (NOVADIS SARL) 18 February 1994 see page 8, line 1 - line 7 see figures 1-5	7

Y	US,A,5 167 614 (TESSMANN TERRI L ET AL) 1 December 1992 see column 2, line 34 - line 38 see column 2, line 44 - line 58 see figures 4-8	8
A	---	1,3,4
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 December 1996	12. 12. 96

Name and mailing address of the ISA	Authorized officer
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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter ional Application No
PCT/GB 96/02212

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 461 791 (BARONE HECTOR D ;PARODI JUAN CARLOS (AR); PALMAZ JULIO C (US)) 18 December 1991 see column 11, line 45 - line 54; figures 10-12	9-13
P,A	DE,A,195 33 589 (MARTIN ERIC C) 14 March 1996 see column 3, line 37 - line 40 see column 3, line 53 - line 60 see figures 1,4	9-13
A	EP,A,0 621 017 (ADVANCED CARDEOVASCULAR SYSTEM) 26 October 1994 see abstract see column 10, line 6 - line 15; figures 1-3,12-22	1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

:rnational application No.
PCT/GB 96/02212

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims 1-12 : Stent made from ring-like rigid member with a shape memory effect.
2. Claim 13 : Graft having a branch tube which can be inverted so as to be housed within the graft.

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. ..nal Application No
PCT/GB 96/02212

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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		DE-T-	68920055	11-05-95
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		US-A-	5522880	04-06-96
		US-A-	5571173	05-11-96
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		CA-A-	2121985	24-10-94
		JP-A-	7000531	06-01-95

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DOCUMENT-IDENTIFIER: WO 9709007 A1
TITLE: A SURGICAL GRAFT/STENT SYSTEM
PUBN-DATE: March 13, 1997

INVENTOR-INFORMATION:

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ASSIGNEE-INFORMATION:

NAME	COUNTRY
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ANSON ANTHONY WALTER	GB

APPL-NO: GB09602212
APPL-DATE: September 6, 1996

PRIORITY-DATA: GB09518400A (September 8, 1995)

INT-CL (IPC): A61F002/06

EUR-CL (EPC): A61F002/06 , A61F002/06

ABSTRACT:

CHG DATE=19990617 STATUS=O>A tubular graft/stent comprises a tubular sheath (10) having at intervals along its length a plurality of ring-like rigid members (11), which are attached to the sheath around their respective circumferences and are made of a

shape memory material, so that when said members (11) change shape the sheath (10) adopts a new cross section in conformity with them along its whole length. The members may be discontinuous to allow the adoption of a contracted shape in the martensitic phase and an expanded shape in the austenitic phase. A graft may also have a side tube (14) which can be inverted so as to be housed within the sheath.